

US EPA ARCHIVE DOCUMENT



VIA E-MAIL

September 15, 2009

Ms. Kelly Sherman  
Office of Pesticide Programs  
U.S. Environmental Protection Agency  
One Potomac Yard (South Building)  
2777 South Crystal Drive  
Arlington, VA 22202

RE: IIRB Submission Package, Dated August 4, 2009

Dear Kelly:

I am responding to your e-mail inquiry dated September 10, 2009, regarding the dates within the Aerosol Study Protocol. The Aerosol Study Protocol submitted to EPA on August 4, 2009 is the same version as the July 14, 2009 version approved by IIRB. First, the inside bottom section of the July 14 protocol submitted to IIRB shows July 13. Sami Selim of the Golden Pacific Laboratories must have prepared the IIRB submission package on July 13, and when submitting the actual package to IIRB on July 14, he changed the cover page date to July 14 and overlooked changing the date in the footer of the subsequent pages. With respect to the AEATF submission to EPA, because of the continuous page numbering requirement and having to do that in a PDF version, I asked my assistant to put the EPA submission date of August 4 on the cover page and in the header of the inside of the protocol. There are two inside headers on top of each page, one for the complete volume 2 and the other just for the protocol itself. The key point is that the protocol submitted to EPA with the cover page date of August 4 is the IIRB approved version.

Sincerely,

A handwritten signature in black ink that reads "Hasmukh Shah".

Hasmukh Shah  
Manager, AEATF

Copy to:  
John Carley, EPA  
Bill Jordan, EPA  
Tim Leighton, EPA  
Cassi Walls, EPA

US EPA ARCHIVE DOCUMENT





VIA E-MAIL

September 18, 2009

Tim Leighton  
Office of Pesticide Programs  
U.S. Environmental Protection Agency  
One Potomac Yard (South Building)  
2777 South Crystal Drive  
Arlington, VA 22202

RE: IIRB Submission Package, Dated August 4, 2009

Dear Tim:

I am responding to your e-mail inquiry of today regarding the aerosol protocol missing what to do if the benchmark accuracy goal is not met (i.e.,  $k=3$ ) once the data are collected and analyzed. On behalf of the AEATF II, I want to confirm that if large deviations from the benchmark goals are observed in the aerosol study, AEATF II will, in consultation with regulatory agencies, determine the best course of action to take. This may mean the development of guidance for the use of these data that takes the increased imprecision of the estimates into account. It is possible that collection of additional clusters might be considered. AEATF II will include this additional step in a revised aerosol study protocol that will be submitted to IIRB following incorporation of any other comments received from EPA and HSRB at the October 21, 2009 meeting.

Sincerely,

A handwritten signature in black ink that reads "Hasmukh Shah".

Hasmukh Shah  
Manager, AEATF

Copy to:  
John Carley, EPA  
Bill Jordan, EPA  
Kelly Sherman, EPA  
Cassi Walls, EPA

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